



0360-51000

C12/3761

PATENT

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THE UNITED STATES PATENT AND TRADEMARK OFFICE

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and Alastair Edwin McAuley

For: BREATHING ASSISTANCE  
APPARATUS

Serial No.: 09/662,203

Filed: September 14, 2000

Art Unit: 3761

Atty Docket No.: 1171/38911/80

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on November 15, 2000.

*Jennifer L. Soukup*  
Jennifer L. Soukup

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REGARDING CONVENTION CLAIM UNDER 35 U.S.C. §119

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In completion of Applicant's claim for priority under 35 U.S.C. §119 for United States Patent application, please find enclosed a true copy of the Provisional Specification as filed on 23 September 1999 with an application for Letters Patent number 337993.

It is believed that this completes Applicant's claim for priority and acknowledgment of receipt of this priority document is requested.

Respectfully submitted,

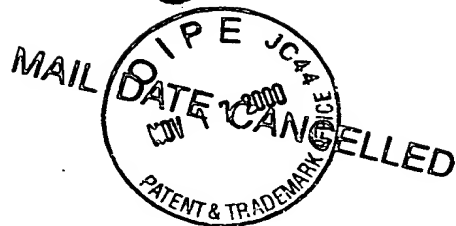
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## CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 23 September 1999 with an application for Letters Patent number 337993 made by FISHER & PAYKEL LIMITED.

Dated 12 October 2000.

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Neville Harris  
Commissioner of Patents



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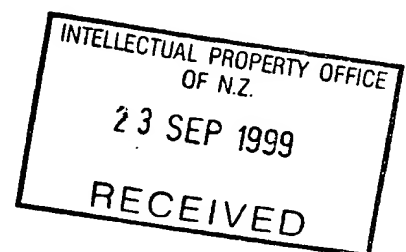
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NEW ZEALAND  
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# PROVISIONAL SPECIFICATION

An Improved Breathing Assistance Apparatus

We, FISHER & PAYKEL LIMITED, of 78 Springs Road, East Tamaki, Auckland, New Zealand, a company duly incorporated under the laws of New Zealand, do hereby declare this invention to be described in the following statement:





This invention relates to valves particularly through not solely for inclusion in the breathing circuit of a respirator.

A medical breathing circuit such as might be used in a Continuous Positive Airway Pressure Respirator (CPAP) includes an inspiratory gases tube which has one end thereof connected to the patient through an interface. For example through an endotracheal breathing tube extending into the trachea and ending just above the lungs. The other end thereof is connected to a respirator providing pressurised gases. The connection to the respirator may be direct or a self contained humidifier may be interposed.

One disadvantage of CPAP treatment is that it effectively reverses the normal breathing function. The patient has to relax to breath in and requires effort to breath out. Since normal breathing requires the exact opposite, the use of CPAP is sometimes difficult initially.

A number of devices exist to reduce the effort required by the patient to exhale. For example US Patent 5,657,752 assigned to Airways Associates describes a variable orifice venting aperture member in the nasal mask to help vent the exhalations. US Patent Number 5,065,756 assigned to New York University includes vent holes in the face mask for rapid discharge of exhaled air. US Patent 4,658,213 assigned to New York University includes a threshold valve to release air from the mask. Alternatively electronic methods exist such as that described in US patent no. 5803065 assigned to Respirationics have been used to improve the effectiveness of CPAP therapy.

However to some degree these existing devices are still somewhat ineffective. Also in some cases these apparatus include a bulky face mask and strapping which may be uncomfortable for the user.

It is an object of the present invention to provide a valve for a respiratory breathing circuit which will obviate the above disadvantage or will at least provide healthcare providers with a useful choice.

Accordingly in a first aspect the present invention may broadly be said to consist in a system for supplying gases to a user at a pressure above ambient comprising:

- a pressurised gases supply,
- gases delivery means in fluid communication with said pressurised gases supply
- and said user, and

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flow control means including a first opening in fluid communication with said gases passageway, a second opening in fluid communication with said gases delivery means, and blocking means adapted such that during said user's inhalation, said gases flow between said pressurised gases supply means and said user, and during said user's exhalation, said gases from said pressurised gases supply are vented externally.

Preferably said flow control means further includes a first auxiliary outlet and a second auxiliary outlet, disposed either side of said blocking means.

Preferably, during inhalation of said user, said first auxiliary outlet and said second auxiliary outlet being closed.

Preferably, during exhalation of a user said first auxiliary outlet and said second auxiliary outlet being open, wherein said first auxiliary outlet being in fluid communication with said pressurised gases supply and said gases from said pressurised gases supply thereby being vented externally, and said second auxiliary outlet being in fluid communication with said user the exhalatory gases from said user thereby being vented externally.

Preferably, said flow control means comprises a body portion, a cylindrical moveable member of a diameter suitable to seal inside said body portion but in use axially moveable therein, and a partition including said blocking means associated with said moveable member.

Preferably said first auxiliary outlet and said second auxiliary outlet comprise apertures in said body portion which are adapted to align with apertures in said moveable member during exhalation of said user, and are adapted to be closed off by sections of said body portion during inhalation of said user.

Preferably said first auxiliary outlet is of an cross sectional area greater than that of said second auxiliary outlet.

Preferably said system further comprises humidification means disposed in the flow path at said gases between said gases supply means and said user, adapted to humidify said gases to a desired level of humidity.

Preferably said flow control means is disposed between said pressurised gases supply and said humidification means.

In a second aspect the present invention can be broadly said to consist in an

apparatus for controlling the gas flow between a pressurised gases supply and a user, comprising:

a body portion including a first opening adapted to be in fluid communication with a pressurised gases supply, a second opening adapted to be in fluid communication with a user and at least one exterior vent, and

valve means adapted such that during a user's inhalation, the flow of gases from said first opening is directed to said second opening, and during a user's exhalation, the flow of gases from said pressurised gases supply is directed to said at least one exterior vent.

In a third aspect the present invention can be broadly said to consist in a valve for controlling the gas flow between a pressurised gases supply and a user, comprising:

a body portion with a first opening and a second opening,

blocking means for allowing flow between said first opening and said second opening in one direction and restricting flow between said first opening and said second opening in the other direction, located between said first opening and said second opening,

a first auxiliary outlet in said body portion on the first opening side of said blocking means, and

wherein, during inhalation of a user, said first auxiliary outlet and said second auxiliary outlet being closed, and during exhalation of a user, said first auxiliary outlet being open,

Preferably said valve further comprises a second auxiliary outlet in said body portion on the second opening side of said blocking means which during inhalation of a user, is closed and during exhalation of a user, is open..

Preferably, said first opening is in fluid communication with a pressurised gases supply.

Preferably, said second opening is in fluid communication with a user.

Preferably, said flow in one direction in use relates to when a user inhales.

Preferably, said flow in the other direction in use relates to when a user exhales.

Preferably, said valve further comprises an axially moveable member of cylindrical construction and a diameter suitable to seal inside said body portion but in use axially moveable therein.

Preferably said first auxiliary outlet and said second auxiliary outlet comprise apertures in said body portion which align with apertures in said moveable member during exhalation of a user, and are closed off by solid sections of said body portion during inhalation of a user.

Preferably said moveable member includes a partition on which said blocking means is located, said partition disposed between said apertures in said moveable member.

Preferably said first auxiliary outlet is of an cross sectional area greater than that of said second auxiliary outlet.

This invention may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, and any or all combinations of any two or more of said parts, elements or features, and where specific integers are mentioned herein which have known equivalents in the art to which this invention relates, such known equivalents are deemed to be incorporated herein as if individually set forth.

The invention consists in the foregoing and also envisages constructions of which the following gives examples.

One preferred form of the present invention will now be described with reference to the accompanying drawings in which;

Figure 1A is a blown out perspective view of the present invention, showing the components that fit together to form the valve,

Figure 1B is a blown out perspective view of the movable valve member according to the preferred embodiment of the present invention,

Figure 2 is a cutaway view of the present invention during inhalation,

Figure 3 is a cutaway view of the present invention during exhalation,

Figure 4 is a graph of a typical pressure/flow rate characteristics of a respirator,

Figure 5 is a block diagram of a typical breathing assistance apparatus circuit, according to the preferred embodiment of the present invention,

Figure 6 is a graph illustrating the typical pressure profile experienced by a patient according to traditional CPAP methods, and

Figure 7 is a graph illustrating the typical pressure profile experienced by a patient according to the preferred embodiment of the present invention.

The present invention attempts to provide a simple to manufacture device which attempts to improve comfort levels for a user undergoing CPAP therapy. This is done by providing a four-way valve in the conduit between the respirator and the patient which allows both gases to flow to the patient and exhalations to be expelled to flow through the same conduit. This makes exhaling easier for the user, without the need for additional apparatus to be worn by the user. If the gases supplied to the user are to be humidified, the valve is positioned between the respirator and the humidifier, i.e. upstream of the humidifier.

Referring now to Figure 1, we see the valve in more detail. The valve body 100 has two ends 102, 104 adapted for connection to a typical respiratory conduit and an enlarged centre section 106 which houses the axially moveable valve member 108. The centre section 106 includes two apertures 110 and 112 on its periphery, located either side of an imaginary central point.

The valve member 108 is of a generally hollow cylindrical construction and includes two matching apertures 114, 116 on its periphery again located either side of an imaginary centre point. Also part of the valve member 108 is a partition 118 which joined to the inner periphery of the valve member in between the two apertures 114, 116. Attached in the centre 122 of the partition 118 is a one-way valve 120 which only allows inhalatory gases to pass and at least partially blocks exhalatory gases.

In the preferred embodiment of the present invention the one way valve 120 is a sealing rubber flap attached to the partition on the patient side. This allows gas to pass from respirator to user (inhalation), but only on a minimal level from user to respirator (exhalation) in Figures 2 and 3. This is because the flap is designed to be not quite large enough to entirely seal around the aperture. Thus a small amount of exhalatory gases may pass.

Referring now to Figures 2 and 3, the operation of the valve is now explained.

During a patient inhalation the valve member is in the open position as shown in Figure 2. The gas flow is as designated by arrow 130, which forces the movable member 108 towards the patient, until it hits the inspiratory stops 134. The apertures in the body portion 110, 112 in this position are closed off and do not match up with the apertures in the valve member 114, 116. In this case the one-way valve is effectively in open position



and provides low resistance through the valve from the respirator to the patient.

When the patient exhales, shown in Figure 3, back pressure results on the patient side of the valve due to the one-way valve 120. This pressure forces the valve member 108 to move towards the respirator, until it hits the expiratory stops 136. Once forced to the "closed" position, the apertures 110, 112 in the body portion and the apertures in the valve member 114, 116 align. This means that gases from the respirator are discharged into the atmosphere, shown by arrow 140 and the exhalatory gases from the patient, shown by arrow 150, are also discharged into the atmosphere. This means that the back pressure that the patient experiences while exhaling is much reduced due to the typical pressure flow rate characteristics of the respirator shown in Figure 4. During inhalation the respirator might operate at point 200. Whereas during exhalation, due to the high flow rate through aperture 110 into the atmosphere, operation might be at point 202 with correspondingly low pressure seen by the patient.

It will be appreciated that the aperture in the valve used to vent the patient's exhalations is only one possible embodiment of the present invention. It would be equally viable to have, for example, a pressure release valve in the circuit near the patient. The advantage of the present invention however is the reduced pressure delivered by the respirator, during exhalation.

Each of the valve body portion 102 and valve member 108 may be simply manufactured by injection moulding, for example a polycarbonate plastics material or other suitable plastics material.

A typical respiratory humidification circuit such as might employ the present invention is shown diagrammatically in Figure 5, and includes the respirator 230, humidifier 231, and the associated respiratory breathing tubes 233 and 234. A patient 236 under treatment is shown connected to the system. As indicated in Figure 5 the valve of the present invention is connected between the humidifier 231 and the outlet port of the respirator 230 and is indicated by reference numeral 237.

A typical pressure profile as might be experienced by a patient treated using the present invention is shown in Figure 7. This illustrates the high pressure during inhalation 300, the point at which the valve vents the respirator output 301, and the relatively low pressure during exhalation 302. This compares with a typical pressure profile of a patient

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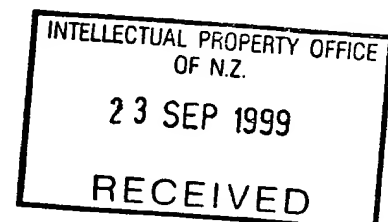
treated without the present invention shown in Figure 6. This illustrates that the pressure experienced during exhalation 308 is similar to that during inhalation 306.

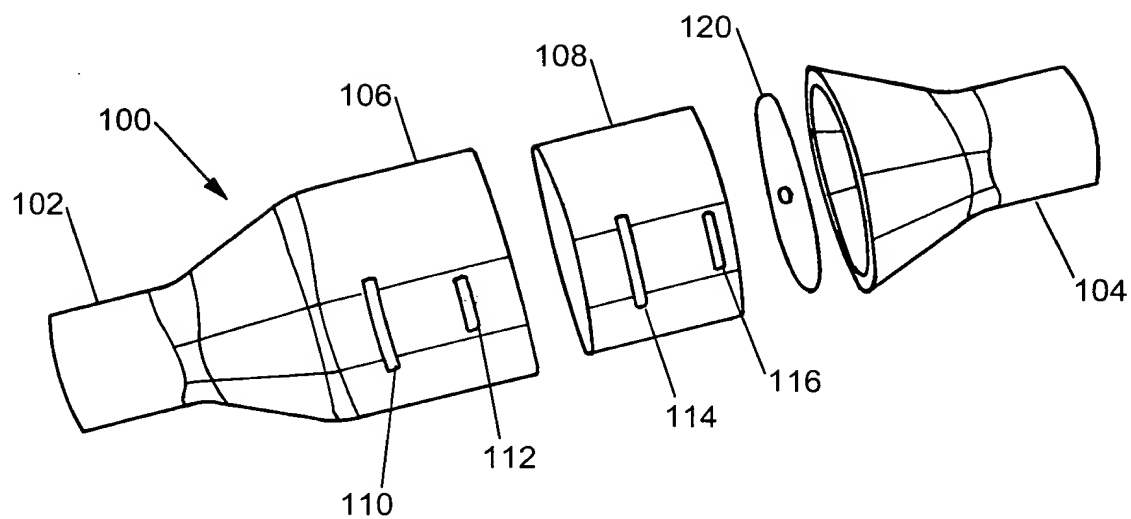
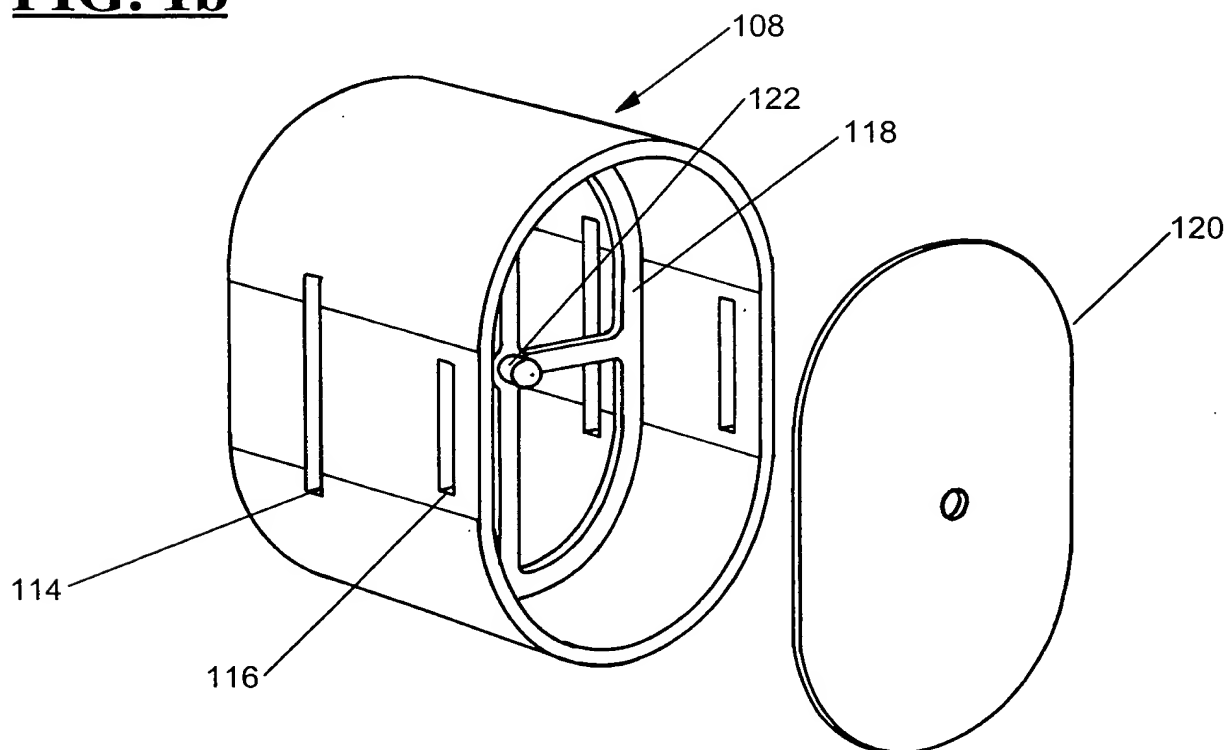
It will be appreciated from the above description that during exhalation the patient does not have to exert as much force to exhale as would normally be the case with traditional CPAP therapy. Thus the present invention provides a simple method of improving the quality of CPAP therapy without increasing the bulk of the apparatus worn by the patient.



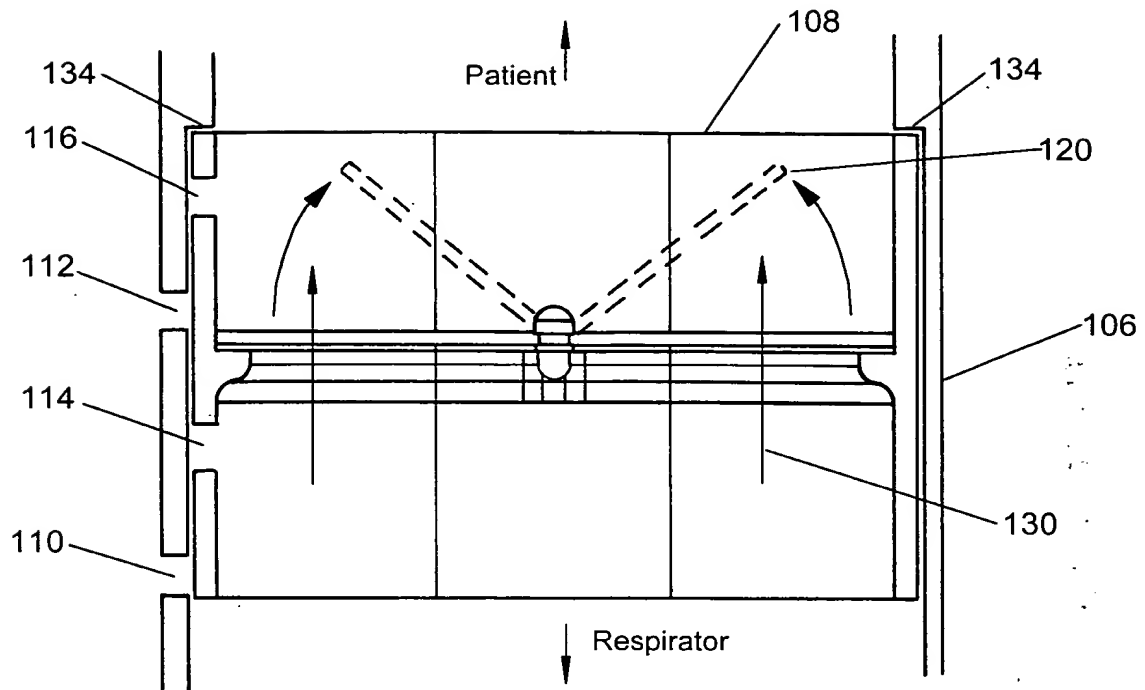
DATED THIS 23<sup>RD</sup> DAY OF September 1999  
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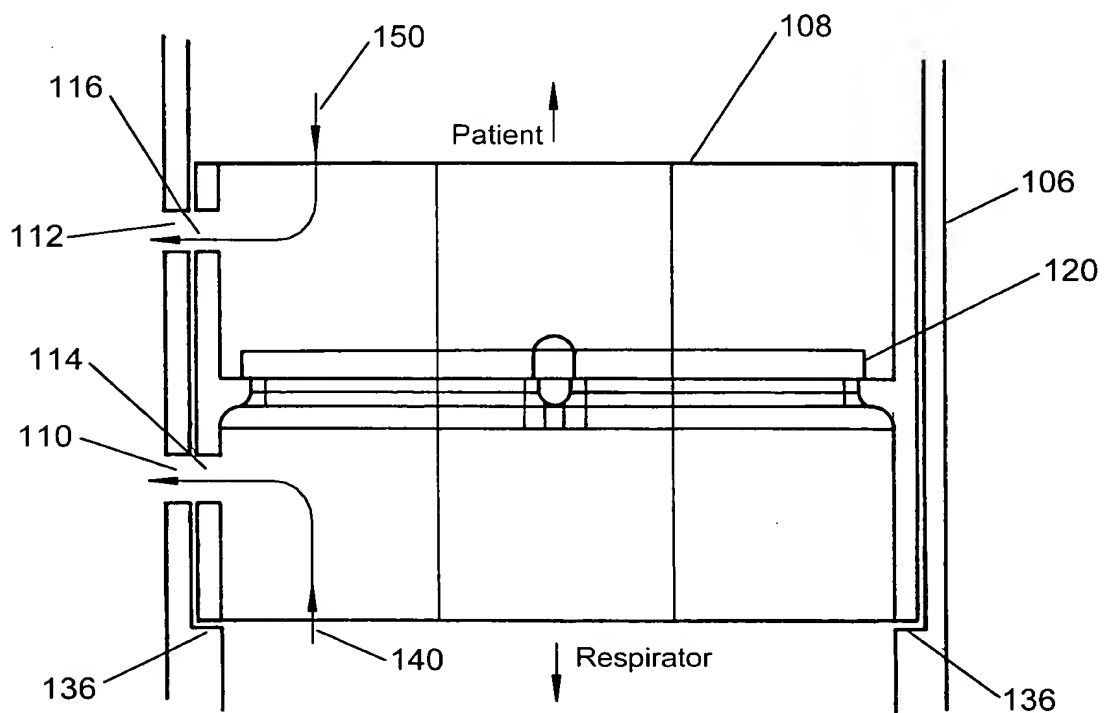


**FIG. 1a****FIG. 1b**

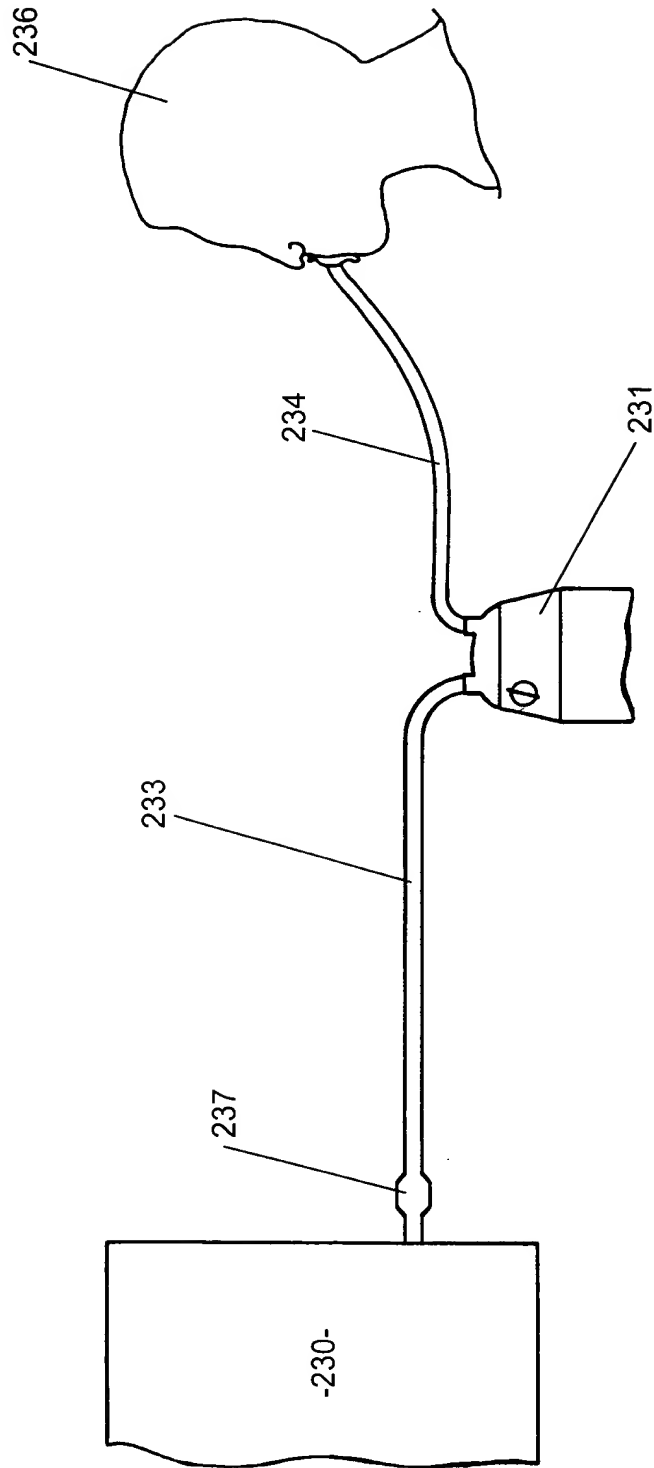
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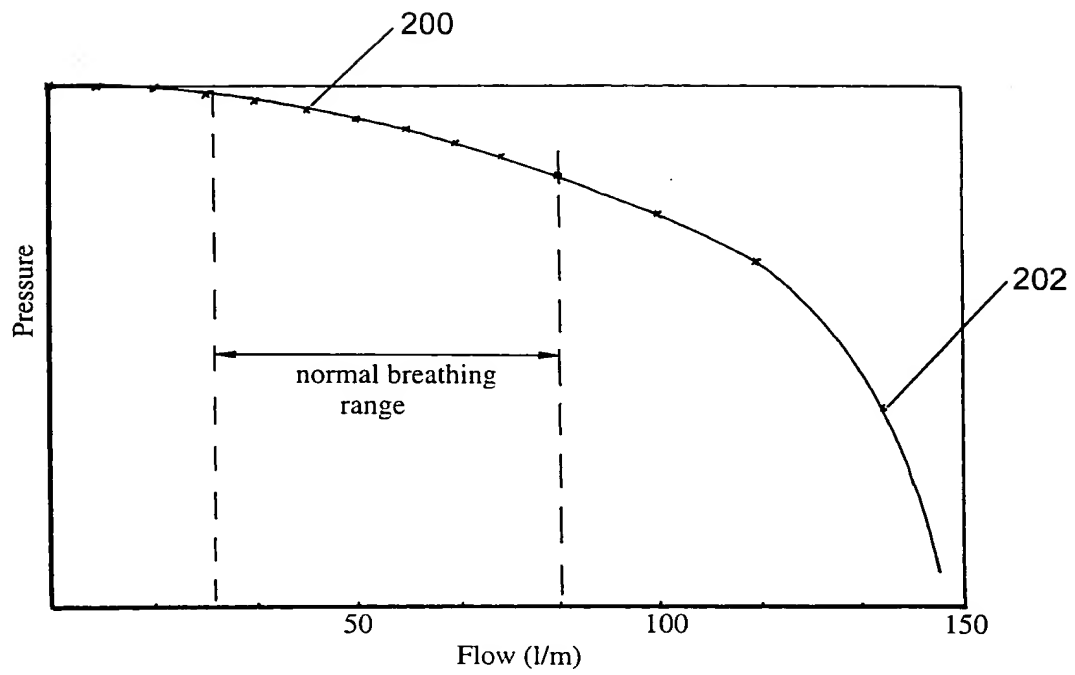
**FIG. 2**



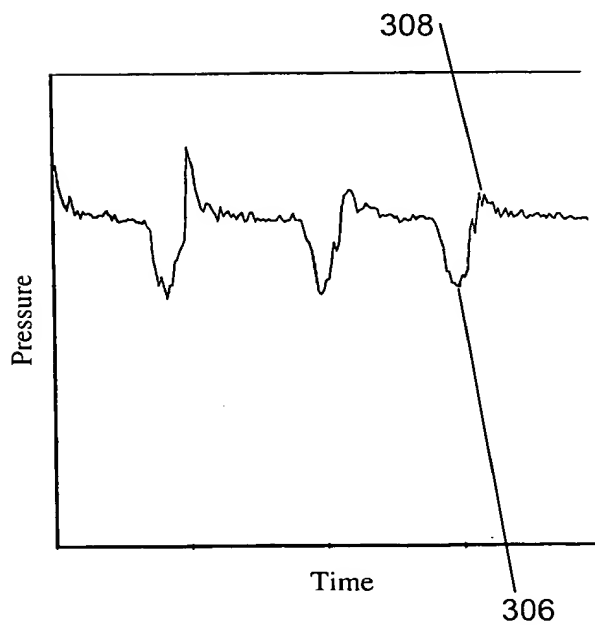
**FIG. 3**



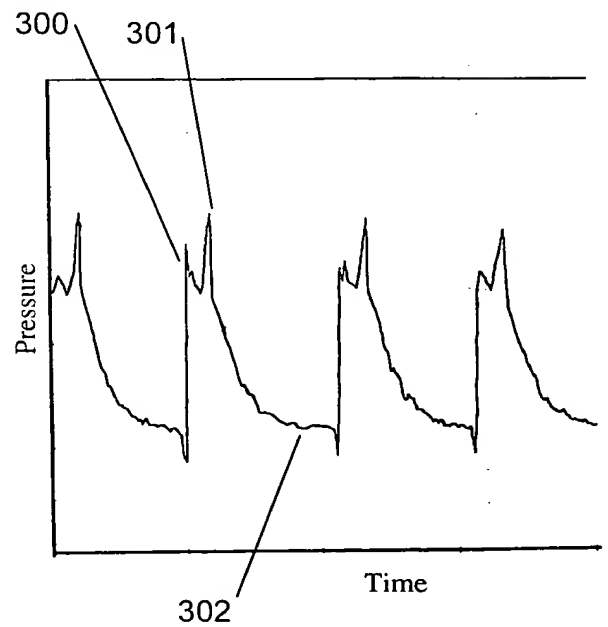
**FIG. 5**



**FIG. 4**



**FIG. 6**



**FIG. 7**